PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference JNR/PG4942	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/10347	International filing date *(day/month/year)* 15.09.2003	Priority date *(day/month/year)* 17.09.2002
International Patent Classification (IPC) or both national classification and IPC A61M15/00		
Applicant GLAXO GROUP LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
22.03.2004	01.12.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Vänttinen, H Telephone No. +49 89 2399-7442

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/10347

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-55 as originally filed

Claims, Numbers

1-42 as originally filed

Drawings, Sheets

1/12-12/12 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 29-32, 42

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 29, 42 are so unclear that no meaningful opinion could be formed *(specify)*:

   see separate sheet

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 30-32

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:

see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. 1-29, 33, 34, 40-42 .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-29,40-42
	No:	Claims	33,34
Inventive step (IS)	Yes:	Claims	1-29,40-42
	No:	Claims	33,34
Industrial applicability (IA)	Yes:	Claims	1-29,33,34,40-42
	No:	Claims	

2. Citations and explanations

see separate sheet

1 Concerning Item IV

1.1 It is clear already a priori that claims 1, 30 and 40 cannot be so linked as to form a single general inventive concept, because they are considered to relate to completely different methods, namely to a **method of loading a housing** for a medicament dispenser (claims 1 and 40) and to a **method for making a preassembly** for being used with the method of loading the housing (claim 30). As far as the arguments of the applicant in the letter of 22.01.04 are concerned, even though claim 30 has a common method step with claims 1 and 40, said method of claim 30 produces a pre-assembly which is used in the method of claim 1. Consequently, claim 30 is considered to relate to a different possible invention.

1.2 In addition, it is clear already a priori that claims 35 and 36 relate to completely different methods than claims 1, 30 and 40, because claims define a method of coiling a medicament carrier.

1.3 The independent product claim 33 is considered to relate to method claim 1.

1.4 In the light of the above, the present set of claims is a priori considered to relate to three different groups of possible inventions, said groups being covered by the following claims: (I) claims 1-29, 33, 34, 40-42; (ii) claims 30-32; and (iii) claims 35-39.

1.5 The claims of group (ii) have not been searched. Furthermore, the applicant did not pay the requested additional examination fees for the group (iii). Consequently, only the claims of group (I) have been examined in respect of Article 33(2)-(4) PCT.

2 Concerning Item III

The product-by-process claims 29 and 42 are not considered to be allowable, because it appears that the skilled person cannot determine from the final product how it has been manufactured. For example, the skilled person cannot determine from a coiled medicament carrier if it has been coiled using especially the methods of claims 35 or 36 or another method yielding the same result. Therefore, claim 39 is not considered to define any technical features of the medicament carrier. A product-by- process claim is only the allowable when the technical effects of the process can be determined from the final product. In the light of the above, said claims do not meet the requirement of Article 6 PCT and cannot be examined in

respect of Article 33(2)-(4) PCT.

3 Concerning Item V

3.1 US-A-2002/053344 (D1, see Figs. 17, 18 and 20) discloses a housing for a medicament dispenser being adapted for loading with a medicament carrier by a method of claim 1, the carrier having a form of an elongated strip (501) and having multiple medicament doses, said housing comprising a body defining a cavity (515) having an access port (see Fig. 20) for receipt of a medicament carrier provided thereto, and a closure (530a) as defined in claim 33. Moreover, the closure (530a) appears to be in the form of a door in hinged relationship with the body. Thus, the subject-matter of claim 33 does not appear to meet the requirements of Article 33(2) PCT. In addition, EP-A-0 467 172 (D2) appears to disclose a device which falls under the wording of claim 33.

3.2 None of the cited documents appears to disclose a method of loading a medicament carrier wherein a leader is first drivably anchored within the housing and the leader is used to move the medicament carrier into the housing. Thus, the subject-matters of claims 1 and 40 and their dependent claims 2-29, 41 and 42 appear to meet the requirements of Article 33(2) and (3) PCT.

3.3 The industrial applicability (Article 33(4) PCT) of a method and device according to the claims 1-29, 33, 34 and 40-42 is self-evident.